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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------|
| 10/788,787 | 02/27/2004 | Jan Peter Sternby | GA-0267-US03 | 6157 |
| 24994 | 7590 | 05/07/2007 | | |
| GAMBRO, INC PATENT DEPARTMENT 10810 W COLLINS AVE LAKEWOOD, CO 80215 | | | EXAMINER DEAK, LESLIE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3761 | |
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| | | | 05/07/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/788,787 | STERNBY ET AL. | |
| | Examiner | Art Unit | |
| | Leslie R. Deak | 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,6-19,22 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,6-19,22 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 4, 6-13, 22, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,177,049 to Schnell et al in view of US 5,687,764 to Tanaka et al.

In the specification and figures, Schnell discloses the apparatus substantially as claimed by applicant. With regard to claims 29, 11, and 22, Schnell discloses a blood processing system comprising an extracorporeal circuit with a flow reversing valve 16 comprising a housing 50 enclosing a chamber 46 with four access openings 54, 56, 58, 60. The access openings are comprised of connectors (see FIG 8) that connect with respective tubing lines 14 (arterial patient line or blood inlet connector), 18 (dialyzer arterial line or circuit inlet connector), 30 (dialyzer venous line or circuit outlet line), and 40 (patient venous line or second blood outlet connector). The system further comprises a dialyzer 26 with inlet 24 connected to circuit inlet connector 18 and outlet 32 connected to circuit outlet connector. The loop further comprises an arterial needle 12 connected to blood inlet connector line 14 and a venous needle 42 connected to blood outlet connector line 40. The system further comprises a movable valve member or

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barrel 64 that moves between various positions in order to adjust the flow connections within the valve (see column 3, line 59 to column 4, line 67, FIGS 1-8).

Schnell fails to disclose that the movable valve member is constructed without dead end portions and of a width less than that of the width of each opening in the valve. Tanaka discloses a switch valve apparatus that is well-known in the art for its simple structure. The valve comprises a housing that encloses a chamber with four openings 102, 103, 104, 105, wherein the valve comprises a movable valve member 106 that is illustrated as having a width narrower than the width of the openings (see column 1, lines 47-67, FIGS 5A, 6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the narrow-vaned valve disclosed by Tanaka for the switch valve in the extracorporeal loop disclosed by Schnell, since Tanaka teaches that such valves are well-known in the art as flow switching valves comprising a simple structure.

While applicant discloses that no portion of the claimed valve has a "dead end" construction, applicant fails to claim any structural limitations that provides such a construction "without dead end portions." As such, it is the position of the examiner that the valve disclosed by Tanaka comprises the construction "without dead end portions" as claimed by applicant, since Tanaka illustrates a cylindrical valve without any particular nooks in which fluid may be trapped.

With regard to claim 4, Tanaka illustrates that the valve member is narrower than the width of the valve openings, which allows the valve member to be arranged in a position in which all four openings are interconnected, as claimed by applicant.

With regard to claims 6-8, Tanaka illustrates that the valve member pivots to various positions within the valve chamber, meeting the claim limitations that the member is capable of being pivoted into the claimed positions. With regard to claims 7 and 8, examiner considers applicant's recitation with regard to the positioning of the valve to be a recitation of the functional operation of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed fails to differentiate from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the valve disclosed by Tanaka is capable of rotating and opening and closing passages as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 9-10, Tanaka illustrates a cylindrical valve in which the openings are spaced 90 degrees relative to each other around the chamber (see FIG 5A).

With regard to claims 12-13, Tanaka illustrates a valve member that forms a partition between two semicircular valve chamber portions.

3. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,177,049 to Schnell et al in view of US 5,687,764 to Tanaka et al, further in view of US 5,443,453 to Walker et al.

With regard to claim 14, Schnell and Tanaka disclose the device substantially as claimed by applicant (see rejection above) with the exception of a wing projection from the valve. Walker discloses a multi-way valve that has a rotatable valve member 13 within body 11, the rotation of which opens and closes various fluid paths (see column

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3, lines 39-62). The valve member comprises handle 12 that extends outside the valve chamber for visual identification of valve position (see column 1, lines 50-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a handle or wing 12 as disclosed by Walker to the extracorporeal system with valve disclosed by Schnell and Tanaka, in order to provide a visual and tactile indication of the valve position, as taught by Walker (see column 1, lines 50-60).

With regard to claims 15 and 16, Schnell and Tanaka disclose the device substantially as claimed by applicant with the exception of a shoulder and a groove to control movement of the valve. Walker specifically discloses that the valve comprises a shoulder 28 the body that interacts with shoulder 27 on the stem to control movement of the valve (see FIG 3, column 4, lines 36-39). Though Walker does not specifically disclose a groove, the absence of material that allows the rotation of the valve to the point of shoulder 27 is considered by the examiner to correspond to applicant's claimed groove, meeting the limitations of the claims. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a shoulder and a groove as disclosed by Walker to the extracorporeal system with valve disclosed by Schnell and Tanaka in order to prevent movement of the valve beyond a certain prescribed position, as taught by Walker (see column 4, lines 36-39).

4. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,177,049 to Schnell et al in view of US 5,687,764 to Tanaka et al in view of US 5,443,453 to Walker et al, further in view of US 4,593,717 to Levasseur.

In the specification and the figures, the prior art discloses the device substantially as claimed by applicant (see rejection above) with the exception of recesses that define valve positions. Levasseur discloses a multi-way valve with a rotating valve stem 40 that puts various passages in fluid communication with one another (see column 2, lines 57-67). Levasseur further discloses that the valve system comprises a detent mechanism to locate the valve stem in the proper position once a particular flow mode is selected (see column 3, lines 42-64). The detent mechanism comprises a number of recesses 70 that cooperate with slot or groove 76. When the valve stem is in the proper position, rod or shoulder 72 drops into the corresponding recess 70 to maintain the valve in the proper position until the operator selects another flow mode. Therefore, it would have been obvious to add the detent mechanism with recesses as disclosed by Levasseur to the valve with groove and shoulder as disclosed by the prior art in order to maintain the valve in the proper position according to the selected flow mode, as taught by Levasseur (see column 3, lines 42-64).

5. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,177,049 to Schnell et al in view of US 5,687,764 to Tanaka et al, further in view of US 4,593,717 to Levasseur.

In the specification and figures, Schnell and Tanaka disclose the device substantially as claimed by applicant (see rejection above) with the exception of the non-symmetrical position of the valve openings and connectors. Levasseur discloses a multi-way valve with a rotating valve stem 40 that puts various passages in fluid communication with one another in a non-90-degree configuration (see column 2, lines

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57-67). Levasseur specifically discloses that entrapment of bubbles in a 90-degree flow conduit is more likely than that in an angled conduit (see column 1, lines 20-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide flow passages at a less than 90-degree angle as disclosed by Levasseur in the valve assembly disclosed by Schnell and Tanaka, in order to prevent bubble entrapment, as taught by Levasseur (see column 1, lines 20-25).

Response to Arguments

6. Applicant's amendment and arguments filed 28 February 2007 have been entered and fully considered.

7. Applicant's arguments with respect to the rejection(s) of the amended claims under Kopf have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Schnell and Tanaka as presented above.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

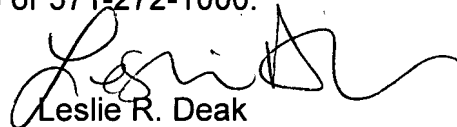
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

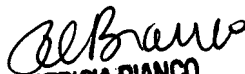
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
17 April 2007



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4-28-07